K102718

Hangzhou Universal Electronic Co., Ltd.

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510(k) Summary

DEC 13 2010

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date of summary was prepared: Aug. 30, 2010

Device

Trade name: **GF-MT501 digital thermometer**

GF-MT502 digital thermometer

Common/Usual name: Digital thermometer

Classification name: Clinical electronic thermometer

Medical specialty (Panel): General Hospital

Regulation number: 880.2910

Product Code: FLL

Classification: Class II

Predicate devices

ECT Digital Thermometer(K101043)/Changshan Estar Electronics Co., Ltd.

Indication for Use

GF-MT501 and **GF-MT502 digital thermometer** are electronic clinical thermometers which are intended to measure the human body temperature in regular mode orally, rectally or underarm. The devices are reusable for clinical or home use on people of all ages.

Device description:

The **GF-MT501** and **GF-MT502 digital thermometer** comprise of a thermistor for measuring sensor, a reference resistor for comparison of the temperature, a buzzer for sounding effect, an ASIC for calculating, and LCD for displaying the measuring temperature digitally for which the thermistor contacts.

The thermometers use a DC 1.5V battery for operation of complete system whenever the battery is low, the ASIC circuit will detect the low battery condition automatically, and displays '▲' in LCD display.

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Statement of substantial equivalence

The **GF-MT501** and **GF-MT502 digital thermometer** are similar in design and intended use to the ECT(K101043) digital thermometer, differing only in physical dimensions. They use a thermistor to measure temperature and comprise of a thermistor for measuring sensor, a reference resistor for comparison of temperature, a buzzer for sounding effect, an ASIC for calculating, and LCD for displaying the measuring temperature digitally for which the thermistor contacts.

While there are minor differences in performance specifications of the thermometers, these differences do not alter the intended use function and use of the device, nor do they raise any new questions pertaining to safety or effectiveness. Therefore, **Hangzhou Universal Electronic Co., LTD.** believes that the **GF-MT501** and **GF-MT502 digital thermometer** are substantially equivalent to legally marketed devices currently in commercial distribution.

Summary of Non-Clinical Testing

The **GF-MT501** and **GF-MT502 digital thermometer** complied with the requirements of ASTM E1112-00 (2006) standard specifications, as well as IEC 60601-1(2005), IEC 60601-1-2(2007), ISO 10993-5(2009) and ISO 10993-10(2002) requirements. Bench testing confirmed the temperature range, accuracy, operating environment, storage environment, resolution, readability and repeatability. For all body contacting materials, analysis is made that the identical materials have been used in other legally marketed devices under the same use conditions.

Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, **Hangzhou Universal Electronic Co., Ltd.** concludes that, **GF-MT501** and **GF-MT502 digital thermometer** are substantially equivalent to predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

International Regulatory Consultants, LLC (IRC)
C/O Mr. Jacob Chang
Beitun District
16F-2(16A), Sec. 2, Chong De Road
Taichung China 406

JAN 12 2011

Re: K102718
Trade/Device Name: GF-MT501 digital Thermometer and GF-MT502 Digital Thermometer
Regulation Number: 21 CFR 880.2190
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: November 5, 2010
Received: November 5, 2010

Dear Mr. Chang:

This letter corrects our substantially equivalent letter of December 13, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices /ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

DEC 1 3 2010

510(k) Number (if known): K102718

Device Name: **GF-MT501 digital thermometer** and
GF-MT502 digital thermometer

Indications for Use:

To measure the human body temperature in regular mode orally, rectally or underarm. The devices are reusable for clinical or home use on people of all ages.

Prescription Use _____ Over-The-Counter Use __X__
(Part 21 CFR 801 Subpart D) AND/OR (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

12/13/10

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K102718

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